## In the Supreme Court of the United States

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

OHIO HOSPITAL ASSOCIATION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

## REPLY BRIEF FOR PETITIONER

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## TABLE OF AUTHORITIES

Cases:	Page
Bowen v. Michigan Academy of Family Physicians,	•
476 U.S. 667 (1986)	1
Heckler v. Ringer, 466 U.S. 602 (1984)	8
	1, 6, 7
Henry v. City of Rock Hill, 376 U.S. 776 (1964)	10
Kapoor v. United States, 516 U.S. 801 (1995)	10
O'Leary v. Mack, 522 U.S. 801 (1997)	10
Shalala v. Illinois Council on Long Term Care, Inc.,	
120 S. Ct. 1084 (2000)	7, 9, 10
913 (1996)	10
United States v. Neifert-White Co., 390 U.S. 228	
(1968)	8
Weinberger v. Salfi, 422 U.S. 749 (1975)	1
Statutes:	
Administrative Procedure Act:	
5 U.S.C. 701(a)(2)	8
5 U.S.C. 702-704	8
5 U.S.C. 704	8
False Claims Act, 31 U.S.C. 3721 et seq.:	
31 U.S.C. 3729	4
Health Insurance for the Aged Act (Medicare Act),	-
42 U.S.C. 1395 et seq.:	
42 U.S.C. 1395ff(b)(1)	4, 5, 6
42 U.S.C. 1395ii	1, 6
28 U.S.C. 1331	1, 4, 6
28 U.S.C. 1346	1, 1, 0
28 U.S.C. 2106	10
42 U.S.C. 405(b)	4
42 U.S.C. 405(g)	4
42. U.S.C. 405(b) 1.2.3.4.6	_

## REPLY BRIEF FOR PETITIONER

1. Respondents do not dispute that this case turns on the proper construction of 42 U.S.C. 405(h), which (as incorporated into the Medicare Act by 42 U.S.C. 1395ii) provides that "[n]o action against the \* \* \* the [Secretary of Health and Human Services] \* \* \* shall be brought under [28 U.S.C. 1331 or 1346] to recover on any claim arising under [the Medicare Act]." 42 U.S.C. 405(h). Nor do respondents dispute that, after the court of appeals issued the decision below, this Court clarified Section 405(h)'s preclusive scope in Shalala v. Illinois Council on Long Term Care, Inc., 120 S. Ct. 1084 (2000). In *Illinois Council*, the Court reaffirmed its prior holdings, in Weinberger v. Salfi, 422 U.S. 749 (1975), and Heckler v. Ringer, 466 U.S. 602 (1984), that Section 405(h) channels virtually all private party challenges to the Secretary's Medicare policies and regulations through the specific administrative and judicial review mechanisms set out in the Medicare Act itself. See Illinois Council, 120 S. Ct. at 1092, 1094. And it clarified that the exception to Section 405(h)'s bar on review under 28 U.S.C. 1331— previously recognized in Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986)—applies only where barring suit under Section 405(h) would not merely delay judicial review, but instead would preclude judicial review altogether. 120 S. Ct. at 1096-1097.

Respondents concede that the question in this case is whether respondents may bring suit under 28 U.S.C. 1331 to challenge the Secretary's policies despite the bar provided by Section 405(h). Br. in Opp. i. And they effectively concede that *Illinois Council* bears strongly on the answer to that question. They argue, however, that this Court need not grant the petition, vacate the judgment, and remand the case for further consideration in light of *Illinois Council* because the decision below is consistent with *Illinois Council*.

Br. in Opp. 12. In particular, they argue that applying Section 405(h) to bar this suit would have the effect of precluding judicial review entirely. Id. at 13. As explained below (pp. 4-6, infra) and in our opening brief (at 3-5, 21-22 nn.13-14), that assertion is incorrect; respondents can obtain judicial review of any adverse action taken against them by the Secretary or the Attorney General. More important for present purposes, however, the court of appeals' decision does not address the extent to which permitting respondents to proceed with this suit is consistent (or inconsistent) with this Court's decision in *Illinois Council*; and for good reason, since that decision was announced months before this Court decided *Illinois Council*. Under such circumstances—where this Court issues a potentially dispositive decision after the court of appeals has issued its decision—this Court's traditional practice is to grant the petition, vacate the judgment of the court of appeals, and remand for further consideration in light of the intervening precedent. We see no reason to depart from that practice here.

2. Respondents, in any event, err in asserting that the court of appeals' decision is consistent with this Court's decision in *Illinois Council*. As we explain in the petition (at 19-20), the decision below appears to hold that Section 405(h) does not apply here because respondents' challenge to the Secretary's Medicare policies does not concern "individual claimants \* \* \* seeking a judgment directing the payment of benefits." Pet. App. 11a. And, as we also explain in the petition (at 19-20), this Court rejected that rationale in *Illinois Council*. Section 405(h), the Court held, cannot be limited "to claims for monetary benefits." 120 S. Ct. at 1094.

Recognizing that difficulty, respondents assert (Br. in Opp. 21) that the Sixth Circuit "did not base its decision on whether this was a claim for benefits." Respondents' assertion is difficult to reconcile with the court of appeals' opinion. The court of appeals first distinguished *Salfi* and *Ringer* on the ground that, unlike the plaintiffs in those

cases, the hospitals here "are not seeking a judgment directing the payment of benefits." Pet. App. 12a (emphasis added). And the court of appeals further declared that Section 405(h) "simply seeks to preserve the integrity of the administrative process Congress designed to deal with challenges to amounts determinations by dissatisfied beneficiaries." Pet. App. 13a (emphasis added). Those assertions are at odds with *Illinois Council's* rejection of a "distinction that limits the scope of § 405(h) to claims for monetary benefits." 120 S. Ct. at 1094. See also id. at 1095 (Michigan Academy does "not limit the scope of § 405(h) itself to instances where a plaintiff, invoking § 1331, seeks review of an 'amount determination.'"); id. at 1096 (limiting Section 405(h) to "amount determinations" would "have created a hardly justifiable distinction between 'amount determinations' and many other similar HHS determinations.").

To support their contrary contention, respondents argue that the court of appeals' reference "to 'amount determinations'" in distinguishing Salfi and Ringer simply served to "highlight[] the fact that a claimant seeking payment of benefits guite clearly has administrative channels" to "traverse before any judicial review can take place." Br. in. Opp. 21. In contrast, respondents contend (at 22) that it is "the unavailability of such procedures in the case at hand \* \* \* which formed the basis for the [court of appeals'] decision." Thus, respondents insist (at 17) that the Sixth Circuit correctly applied the exception to Section 405(h) "subsequently adopted by the *Illinois Council* majority," even though the court of appeals did not have the benefit of Illinois Council to guide it. We disagree. The court of appeals did not invoke claims for benefits as an example of a situation where a litigant can invoke administrative procedures; the word "example" is not even used. Instead, most naturally read, the court of appeals' decision invokes claims for benefits as the limiting principle, i.e., it appears to hold that, unless the suit is a claim for benefits, Section 405(h)

simply does not apply. See, *e.g.*, Pet. App. 11a, 13a. Even if that were more doubtful, however, the court of appeals should be given the opportunity to reconsider the case and issue a decision that is more clearly consistent with *Illinois Council*.

More fundamentally, respondents simply err when they assert (Br. in Opp. 16) that this case falls within the exception to Section 405(h)'s preclusive scope recognized by this Court in *Illinois Council*. As explained above (p. 1, supra), and in our opening brief (at pp. 20-21), Illinois Council clarified that the exception to Section 405(h)'s preclusive scope first recognized in Michigan Academy is limited to instances where applying Section 405(h) to bar suit under 28 U.S.C. 1331 would not merely delay review, but "would mean no review at all." 120 S. Ct. at 1095-1096. In this case, applying Section 405(h) would merely delay review—and would not preclude review altogether—because respondents could obtain judicial review of any governmental action taken against them based on the Secretary's Medicare policies. For example, as the court of appeals acknowledged, any time the Secretary makes a reimbursement determination or seeks recoupment for overpayments based on the challenged policies, respondents will be able to seek administrative and then judicial review pursuant to Sections 405(b) and (g), as incorporated into Medicare by 42 U.S.C. 1395ff(b)(1). See Pet. App. 4a, 33a. Moreover, if the Attorney General were to rely on the Secretary's policies in proceeding against respondents through a False Claims Act suit, 31 U.S.C. 3729, respondents would not merely be entitled to judicial review; they would be entitled to a judicial determination on the issue of liability in the first instance. Indeed, under the False Claims Act, respondents could prevail even if they violated the Secretary's policies; the government would be charged with proving that respondents knowingly submitted claims that were false. See Pet. App. 33a (noting scienter requirement).

For that reason, the court of appeals erred in relying on the fact that "[t]he hospitals had no opportunity to invoke administrative procedures in connection with the disputes that led to the filing of the instant lawsuit, the Secretary never having taken the type of administrative action from which administrative appeals could be prosecuted." Pet. App. 5a. The hospitals have not had the opportunity to invoke the administrative and judicial review mechanisms provided by Medicare because 42 U.S.C. 1395ff(b)(1) defers judicial review until the Secretary takes some action with respect to reimbursement (denial or re-Similarly, the hospitals have not had an coupment). opportunity for judicial consideration of their potential liability under the False Claims Act because the False Claims Act provides for judicial determinations only when and if the government initiates an action by formally filing a suit alleging actual liability on their part.

The court of appeals thus clearly confused the question of the availability of review with its timing. Any time the policies respondents seek to challenge are applied to them, they will have the opportunity to challenge them in court; they simply must wait for the policies to be applied to them. Indeed, in that respect, this case is indistinguishable from Illinois Council. See Pet. 22-24. In Illinois Council, the plaintiff association complained that its members could not obtain judicial review until after the Secretary had imposed a sanction on them for violating the regulations. See 120 S. Ct. at 1097; Pet. 23. They thus, like respondents here, had not had an "opportunity to invoke \* \* \* administrative procedures in connection" with their challenge because, in that case too, the Secretary had not "taken the type of action from which appeals could be prosecuted." This Court nevertheless held that the plaintiff's members were required to await action from the Secretary before seeking review. The court of appeals offered no reason for the different result it

reached in this case. Nor do respondents do so in their brief in opposition.

Moreover, in *Illinois Council*, this Court further explained that hardships from delay are not sufficient to permit immediate review under 28 U.S.C. 1331, unless they are so extreme as to convert "what appears to be simply a channeling requirement into complete preclusion of judicial review." 120 S. Ct. at 1098. The Court concluded in that case that "the Council has not shown anything other than potentially isolated instances of the inconveniences sometimes associated with the postponement of judicial review." Id. at 1099. The same is true here. Nowhere did the court of appeals offer any reason why judicial review cannot be deferred, consistent with 42 U.S.C. 1395ff(b)(1), until such time as the Secretary takes adverse action against respondents. The only hardship associated with deferring judicial review that respondents identify here is the possibility of being subject to a False Claims Act suit. See Br. in Opp. 8, 19. But that does not mean that respondents will be denied judicial review altogether. If the Attorney General does proceed against respondents' member hospitals under the False Claims Act, those members will have the opportunity for a judicial determination of their liability under the False Claims Act itself. Moreover, the dilemma faced by respondents and their members here is no different from that faced by all potential civil litigants. They may wait for litigation

<sup>&</sup>lt;sup>1</sup> Similarly, in *Ringer*, judicial review was available only after the individual had undergone the medical procedure. In that case, one of the plaintiffs asserted that the policy he sought to challenge precluded him from undergoing the medical procedure that was a prerequisite to administrative and judicial review; no physician would perform the operation, he argued, in light of the Secretary's announced policy of not paying for it, and it was the non-payment policy that he sought to challenge. This Court nonetheless held that Section 405(h), as incorporated into Medicare by 42 U.S.C. 1395ii, bars recourse to an anticipatory declaratory judgment action under 28 U.S.C. 1331. 466 U.S. at 622. See also Pet. 23-24.

and maintain their defenses (risking enhanced financial exposure), or they may settle to minimize risk. Pet. App. 28a.

Despite that fundamental flaw in the court of appeals' analysis, respondents attempt to defend the court of appeals' decision on the ground that "[t]he opinion makes no reference to the 'timing' of administrative review." Br. in Opp. 20. But the reason why the opinion does not mention "timing" is that it fails to recognize the significance of the difference between the *current* unavailability of judicial review (a timing issue) and a *total* preclusion of review (an availability issue). Since this Court emphasized that distinction in *Illinois Council*, 120 S. Ct. at 1097, the court of appeals should be given the opportunity to reconsider its decision.<sup>2</sup>

3. Alternatively, respondents argue (Br. in Opp. 17-18) that Section 405(h) is inapplicable here because this dispute arose in the context of a False Claims Act investigation. Respondents argue that the Secretary should not, "[b]y her choice of forum, \* \* \* be permitted to shield her action from judicial review." Br. in Opp. 18. Respondents, however, overlook the fact that no False Claims Act suit was ever initiated against any of respondents' member hospitals. They also overlook the fact—recognized by the district court and the court of appeals (Pet. App. 15a, 28a)—that the Attorney General, and not the Secretary, has exclusive enforcement discretion under the False Claims Act. See Heckler v. Chaney, 470 U.S. 821, 835 (1985). And they over-

<sup>&</sup>lt;sup>2</sup> For the same reason, respondents' speculation (Br. in Opp. 19) that the "[Secretary] has not and will not" actually apply the challenged policies to the hospitals—either in an initial determination or in a reopening of prior payment determinations—is beside the point. If the Secretary does not apply the challenged policies to respondents, respondents have no basis for haling the Secretary into court. And, if the Attorney General does rely on the challenged policies in False Claims Act suits against one of more of respondents' member hospitals in the future, the defendants in those suits will have an opportunity to litigate all relevant issues in court in the context of those suits.

look the fact that invocation of the False Claims Act would not deny any hospital an opportunity for judicial review of any adverse action that is actually taken against it. To the contrary, as we have said, should a False Claims Act suit ever be filed, the defendants will be able to obtain a judicial determination regarding their liability under that Act. See pp. 6-7, *supra*; Pet. App. 15a.<sup>3</sup> Thus, the possibility that the Attorney General may file a False Claims Act suit in the future does not render judicial review "unavailable" under this Court's decision in *Illinois Council*.<sup>4</sup>

4. Respondents also assert (Br. in Opp. 18) that Section 405(h) is inapplicable here because the hospitals "are not seeking to recover any claim." That argument, too, is inconsistent with *Illinois Council*. In *Illinois Council*, the question before the Court was whether the phrase "to recover on

<sup>&</sup>lt;sup>3</sup> Moreover, the False Claims Act seeks to vindicate governmental interests separate and distinct from simply collecting Medicare overpayments in an administrative recoupment proceeding. See generally *United States* v. *Neifert-White Co.*, 390 U.S. 228, 232 (1968).

<sup>&</sup>lt;sup>4</sup> Respondents' reliance on the possibility of a future False Claims Act suit to justify this suit is particularly unpersuasive given the fact that they cannot, by means of a declaratory judgment action, obtain relief with respect to the mere possibility of such a suit. First, respondents cannot identify a cause of action and corresponding waiver of sovereign immunity that would permit them to bring legal action against the Attorney General other than that provided by the Administrative Procedure Act (APA), 5 U.S.C. 702-704. But the cause of action and waiver of immunity provided by the APA only extend to suits challenging final agency action. 5 U.S.C. 704. Here, the Attorney General has not taken final action; there has only been an investigation. See FTC v. Standard Oil Co., 449 U.S. 232 (1980). Moreover, the APA provides for review only if there is no other available remedy. See 5 U.S.C. 704. Here there is a remedy—contesting in court any False Claims Act suit that is actually brought. Nor would any action lie to contest the Attorney General's contemplation of a False Claims Act suit, since she in the end may decline to proceed; and such an action would in any event constitute an anticipatory attack on the exercise of the Attorney General's enforcement discretion, a matter committed to her discretion by law. See 5 U.S.C. 701(a)(2).

a claim" extends only to situations "where an individual seeks a monetary benefit," or instead also includes cases (like *Illinois Council* and this case) where a plaintiff "who might later seek money or some other benefit from (or contest the imposition of a penalty by) the agency challenges \* \* \* the lawfulness of a policy, regulation, or statute that might later bar recovery of that benefit (or authorize the imposition of the penalty)." 120 S. Ct. at 1092. After reviewing the statutory text and its precedents, the Court adopted the latter, broader construction. The phrase "to recover on a claim," the Court held, does not limit Section 405(h)'s application to "actual present" claims, but also includes challenges to regulations that could lead to "potential future" claims as well. Id. at 1094. Indeed, in Illinois Council itself, the respondent did not seek an award of money; instead, it sought to challenge policies and regulations which, in the future, might have led to liability for its members. Respondents in this case likewise challenge the Secretary's regulations in an effort to avoid potential future liability. See Pet. App. 31a ("At bottom, this is a request for an adjudication of the propriety of past payment of benefits, which \* \* \* is a claim that arises under the Medicare Act.").

5. Finally, respondents contend (Br. in Opp. 22-25) that the Court should not grant the petition, vacate the judgment below, and remand to the court of appeals in light of *Illinois Council* because the court of appeals fully considered that decision, which was brought to its attention in a petition for rehearing. The court of appeals, however, made no effort to reconcile its decision with this Court's decision in *Illinois Council*; and respondents themselves struggle in vain to distinguish that intervening decision. See pp. 5-7, *supra*. Indeed, to the extent the court of appeals' order denying rehearing is relevant (see Br. in Opp. 23), it only underscores the court of appeals' failure to address the matter. As we point out in the petition (at 25 n.15), the court of appeals denied rehearing on the ground that "the issues raised in the

petition were fully considered upon the original submission and decision of the case." Pet. App. 36a. But it is simply not possible that the court of appeals "fully considered" this Court's decision in Illinois Council when the case was originally submitted and decided, since Illinois Council was decided on February 29, 2000, some two months after the panel issued the judgment below on December 29, 1999. In analogous situations, "where, not certain that the case was free from all obstacles to reversal on an intervening precedent," the Court has "remand[ed] the case to [the rendering] court for reconsideration." Henry v. City of Rock Hill, 376 U.S. 776, 776 (1964) (per curiam); see *Thomas v. American* Home Prods., Inc., 519 U.S. 913, 915 (1996) (Scalia, J., concurring) (discussing Court's "routine[]" practice of vacating and remanding to allow court of appeals to consider intervening Supreme Court decisions); O'Leary v. Mack, 522 U.S. 801 (1997) (vacating and remanding case to court of appeals for further consideration in light of intervening Supreme Court precedent); Kapoor v. United States, 516 U.S. 801 (1995) (same); see also 28 U.S.C. 2106 ("[t]he Supreme Court \* \* \* may \* \* \* vacate \* \* \* any judgment, decree, or order of a court lawfully brought before it for review, and may remand the cause and \* \* \* require such further proceedings to be had as may be just under the circumstances"). That course is likewise appropriate here.

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For the reasons stated above and in the petition for writ of certiorari, it is respectfully submitted that the petition should be granted, the judgment below vacated, and the case remanded to the court of appeals for further consideration in light of *Shalala* v. *Illinois Council on Long Term Care*, *Inc.*, 120 S. Ct. 1084.

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DECEMBER 2000